

I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, with Express Mail Label No. EL 523936093US on this date: Dec 19, 2000 By: [Signature]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Dong, Liang-Chang et al.

Serial No.: Not Assigned

Filed: Herewith

For: Dosage Form Comprising  
Liquid Formulation

Group Art Unit: Not Assigned

Examiner:

**Preliminary Amendment**

Honorable Commissioner of  
Patents and Trademarks  
Washington, D.C. 20231

Sir/Madam:

PRELIMINARY AMENDMENT

Please amend the application filed herewith as follows:

IN THE CLAIMS

Cancel claims 2-11.

Add new claims 12 - 24 as follows:

12. A sustained-release, liquid formulation dosage form comprising a capsule comprising an expandable layer which expands upon contact with fluid; and a liquid, drug layer consisting essentially of a drug, a surfactant, and a member selected from the group consisting of a mono- and di-glyceride.

13. The dosage form of claim 12 wherein the expandable layer comprises an

osmotic hydrogel, an osmotically effective solute, and a hydroxyalkylcellulose.

14. The dosage form of claim 13 comprising a semipermeable membrane surrounding the capsule and having an exit orifice formed or formable therein.

15. The dosage form of claim 14 wherein the membrane comprises a cellulose acetate and a polyethylene glycol.

16. The dosage form of claim 14 wherein the drug is selected from the group consisting of a peptide, protein, protein anabolic hormone, growth promoting hormone, endocrine system hormone, porcine growth promoting hormone, bovine growth promoting hormone, equine growth promoting hormone, human growth promoting hormone, hormone derived from a pituitary gland, hormone derived from a hypothalamus gland, recombinant DNA, samatotropin, gonadotropic releasing hormone, follicle stimulating hormone, luteinizing hormone, LH-RH, insulin, colchicine, chorionic gonadotropin, oxytocin, vasopressin, desmopressin, adrenocorticotrophic hormone, prolactin, bypressin, thyroid stimulating hormone, secretin, pancreozymin, enkephalin and glucagon.

17. The dosage form of claim 14 wherein the surfactant is selected from the group consisting of polyoxyethylenated castor oil comprising 9 moles to 52 moles of ethylene oxide, polyoxyethylenated sorbitan monopalmitate comprising 20 of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 4 moles of ethylene oxide, polyoxyethylenated sorbitan tristearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan trioleate comprising 20 moles of ethylene oxide, polyoxyethylenated stearic acid comprising 8 moles of ethylene oxide, polyoxyethylene lauryl ether, polyoxyethylenated stearic acid comprising 40 moles to 50 moles of ethylene oxide, polyoxyethylenated stearic acid comprising 50 moles of ethylene oxide, polyoxyethylenated stearyl alcohol comprising 2 moles of

Accepted for Publication

ethylene oxide, and polyoxyethylenated oleyl alcohol comprising 2 moles of ethylene oxide.

18. A sustained-release, liquid formulation dosage form comprising a capsule comprising an expandable layer which expands upon contact with fluid; and a liquid, drug layer consisting essentially of a drug, a surfactant, and an oil selected from the group consisting of a vegetable, mineral, animal and marine oil, an ester of an unsaturated fatty acid, a monoglyceride, a diglyceride, a triglyceride, an acetylated glyceride, olein, palmitin, stearin, lauric acid hexylester, oleic acid, oleylester, glycolized ethoxylated glycerides of oils, fatty acids comprising 13 molecules of ethyleneoxide, and oleic acid decylester.
19. The dosage form of claim 18 wherein the expandable layer comprises an osmotic hydrogel, an osmotically effective solute, and a hydroxyalkylcellulose.
20. The dosage form of claim 19 comprising a semipermeable membrane surrounding the capsule and having an exit orifice formed or formable therein.
21. The dosage form of claim 20 wherein the membrane comprises a cellulose acetate and a polyethylene glycol.
22. The dosage form of claim 20 wherein the drug is selected from the group consisting of a peptide, protein, protein anabolic hormone, growth promoting hormone, endocrine system hormone, porcine growth promoting hormone, bovine growth promoting hormone, equine growth promoting hormone, human growth promoting hormone, hormone derived from a pituitary gland, hormone derived from a hypothalamus gland, recombinant DNA, samatotropin, gonadotropic releasing hormone, follicle stimulating hormone, luteinizing hormone, LH-RH, insulin, colchicine, chlorionic gonadotropin, oxytocin, vasopressin, desmopressin, adrenocorticotrophic hormone, prolactin, bypressin, thyroid stimulating hormone, secretin, pancreozymin, enkephalin and glucagon.

23. The dosage form of claim 20 wherein the surfactant is selected from the group consisting of polyoxyethylenated castor oil comprising 9 moles to 52 moles of ethylene oxide, polyoxyethylenated sorbitan monopalmitate comprising 20 of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 4 moles of ethylene oxide, polyoxyethylenated sorbitan tristearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan monostearate comprising 20 moles of ethylene oxide, polyoxyethylenated sorbitan trioleate comprising 20 moles of ethylene oxide, polyoxyethylenated stearic acid comprising 8 moles of ethylene oxide, polyoxyethylene lauryl ether, polyoxyethylenated stearic acid comprising 40 moles to 50 moles of ethylene oxide, polyoxyethylenated stearic acid comprising 50 moles of ethylene oxide, polyoxyethylenated stearyl alcohol comprising 2 moles of ethylene oxide, and polyoxyethylenated oleyl alcohol comprising 2 moles of ethylene oxide.

24. The dosage form of claim 20 wherein the membrane comprises a thermoplastic polymer composition having a softening point of 40°C to 180°C.

#### **IN THE SPECIFICATION**

On page 1, under subheading REFERENCE TO RELATED APPLICATIONS, first paragraph, line 1, after the word "application", insert -- is a continuation of US Application Serial No. 09/353,702, filed July 14, 1999, now US Patent No. , which - -.


#### **REMARKS**

In accordance with usual practice, please calculate the filing fee in the above-identified accompanying application after cancellation of claims 2-11 and

The specification is being amended to identify the related parent application of which this application is a continuation.

Respectfully submitted,

Dated: 12-19-00

  
John A. Dhuey  
Registration Number 26,265  
Attorney for the Applicants

ALZA Corporation  
1900 Charleston Road  
P.O. Box 7210  
Mountain View, CA 94039-7210  
650-564-5699